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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Sadanobu Shirai

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EXAMINER

MERCIER, MELISSA S

ART UNIT

PAPER NUMBER

1615

MAIL DATE

DELIVERY MODE

11/23/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/542,932	Applicant(s) SHIRAI, SADANOBU	
	Examiner MELISSA S. MERCIER	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 October 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-8,10-12,16-20 and 22-24 is/are pending in the application.
- 4a) Of the above claim(s) 3,7,10,12,17,18,20 and 24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-2, 5-6,8,11,16,19,22-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8-5-09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 20, 2009 has been entered.

Claims 1-3, 5-8, 10-12, 16-20, and 22-24 remain pending in this application. Claims 3, 7, 10, 12, 17-18, 20, and 24 remain withdrawn from consideration. Claims 1-2, 5-6, 8, 11, 16, 19, 22-23 remain under prosecution in this application.

Information Disclosure Statement

Receipt of the Information Disclosure Statement filed on August 5, 2009 is acknowledged. A signed copy is attached to this office action.

Maintained Rejections/Objections

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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Claims 1-2, 5-6, 8, 11, 16, 19, and 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mooney et al. (US Patent 5,814,031) in view of Muta et al. (US Patent 6,432,431).

Mooney discloses a structured occlusive dressing. The dressing can be applied directly to a wound, or may be coated directly onto a film or fiber substrate which is, in turn applied to the wound and surrounding skin (column 2, lines 16-36).

The films may be composed of one or more polymers including polyethylene (column 6, lines 22-29), which is a soft plastic resin and the specific resin of claims 6, and 14-16.

The dressings may also be coated onto a fiber substrate which, in turn, is adhesively or otherwise attached to a film substrate. As discussed previously, the claims are drawn to a product prepared by a particular process; patentability is based on the final product. Applicant is invited to present evidence as to the criticality of the heat fusing means of attachment if it results in a different product being formed.

Mooney discloses fiber substrates including fabrics that are knitted such as modified entangled fiber composed of rayon polyesters, such as 90:10 polypropylene-rayon blends (column 6, lines 30-41), which is the particular combination disclosed in instant claims 6 and 14-16.

Mooney additionally discloses generic teachings of adhesive surfaces applied to the film (Example 1).

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Mooney does not disclose the thickness of the support film being 3-35um.

Mooney additionally does not disclose the particular adhesive composition of instant claims, which is:

- a. water
- b. a moisture retaining agent
- c. polyacrylic acid and/or its salts
- d. a cellulose derivative
- e. a slight soluble polyvalent metal salt
- f. a pH controlling agent

Muta discloses cataplasms comprising a base of the gel patch containing:

- a. 20-70 % by weight water (column 4, lines 60-62),
- b. A moisturizer such as glycerin or propylene glycol can also be added in the amount of 10-60% by weight (column 5, lines 9-16).

c and d (in combination). water soluble polymers including carboxymethylcellulose sodium, hydroxypropyl cellulose, and polyacrylic acid, which are cross linked with an organic or inorganic crosslinking agent. The polymers may be used alone or in combination and are present in the amount of 0.1-30% by weight (column 4, line 63 through columns 5, line 8).

e. the cross linking agents include polyvalent metal compounds such as aluminum hydroxide and dihydroxyaluminium aminoacetate in the amount of 0.0—5% by weight (column 5, lines 22-34).

f. additives, including pH adjusters (column 5, lines 16-19 and 38-40).

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Muta does not disclose the amount of pH adjuster employed or the final pH of the gel base, however, Applicant is reminded that where the general conditions of the claims are met, burden is shifted to applicant to provide a patentable distinction. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. See *In re Aller*, 220 F.2d 454, 105 USPQ 233,235 (CCPA 1955).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have used the adhesive composition of Muta with the dressing of Mooney since each of the references teach that patches would comprise adhesive layers, for application of compositions to the skin, it would have been obvious to combine these adhesives with the expectation that such a combination would have the desired effectiveness, such as an adhesive composition has an adhesive strength stable over time and exhibits neither bleeding due to phase separation in the base nor so called stickiness due to the decrease of the adhesive force of the base.

Applicants attention is drawn to MPEP 2113, regarding Product by Process claims; which recites: “[E]ven though product-by-process claims are limited by and defined by the process; determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)

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Additionally, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used a thinner support based on the needs of the device. Mooney discloses the function of the support is to provide a base for maintaining a cover over the wound, therefore, it would have been obvious to the skilled artisan to utilize a thinner or thicker support based on the needs of the device.

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive.

Applicant argues:

***the heat fusing of the support provides a materially distinct structure.**

Applicant has not provided evidence of the distinct structure. Applicant merely provides allegations that the binding between the support material and an occlusive material is not so strong and therefore, in the case of peeling off, there is a "possibility" that the occlusive composition will still remain on the skin. Speculative possibilities do not take the place of factual experimental evidence. Applicant is invited to provide evidence, such as in the form of a side by side comparison of the supports to show the distinction.

***the dressing of Mooney has a porous cover as an essential component.**

It is respectfully submitted that the instant claims do not exclude the presence of such a cover. The claims only limit the particular support and adhesive layer.

***there is a possibility that the adhesive used in Mooney could permeate into an occlusive composition through a support material, whereas in the instant claims, there is no fear of such.**

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Speculative possibilities do not take the place of factual experimental evidence. Applicant is invited to provide evidence, such as in the form of a side by side comparison of the supports to show the distinction.

***Muta discloses cataplasms comprising a base of a gel patch.**

Muta is relied on the teaching of a specific adhesive composition. The skilled artisan would readily recognize that the adhesive disclosed could be used in other bandage systems and retain the same functional properties described.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA S. MERCIER whose telephone number is (571)272-9039. The examiner can normally be reached on 8:00am-4:30pm Mon through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melissa S Mercier/
Examiner, Art Unit 1615

/Robert A. Wax/
Supervisory Patent Examiner, Art Unit 1615